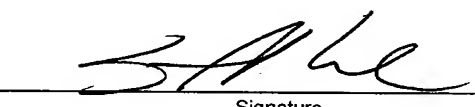


Doc Code: AP.PRE.REQ

PTO/SB/33 (09-08)  
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PRE-APPEAL BRIEF REQUEST FOR REVIEW		Docket Number (Optional)	
		2236.0180000/JUK/SMW	
I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)]  on _____  Signature _____  Typed or printed name _____	Application Number	Filed	
	10/551,466	August 7, 2006	
	First Named Inventor		
	Ji Hoon JEONG		
	Art Unit	Examiner	
	1635	Pitrak, Jennifer K.	
Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.			
This request is being filed with a notice of appeal.			
The review is requested for the reason(s) stated on the attached sheet(s). Note: No more than five (5) pages may be provided.			
I am the			
<input type="checkbox"/> applicant/inventor.		Signature	
<input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)		Scott M. Woodhouse	
		Typed or printed name	
<input checked="" type="checkbox"/> attorney or agent of record.	Registration number 54,747	(202) 371-2600	
		Telephone number	
<input type="checkbox"/> attorney or agent acting under 37 CFR 1.34.	Registration number if acting under 37 CFR 1.34 _____	December 17, 2008	
		Date	
NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.			
<input type="checkbox"/> *Total of _____ forms are submitted.			

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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917565.1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

JEONG *et al.*

Appl. No.: 10/551,466

371(c) Date : August 7, 2006

**For: Conjugate for Gene Transfer  
Comprising Oligonucleotide and  
Hydrophilic Polymer, Polyelectrolyte  
Complex Micelles Formed from the  
Conjugate, and Methods for  
Preparation Thereof**

Confirmation No.: 4435

Art Unit: 1635

Examiner: Pitrak, Jennifer K.

Atty. Docket: 2236.0180000/JUK/SMW

**Arguments to Accompany the Pre-Appeal Brief Request for Review**

*Mail Stop AF*

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

Sir:

Applicants hereby submit the following Arguments, in five (5) or less total pages, as attachment to the Pre-Appeal Brief Request for Review (Form PTO/SB/33). A Notice of Appeal is concurrently filed.

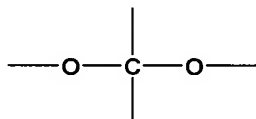
***Arguments***

Applicants respectfully traverse the rejections set forth with respect to claims 1-8 in the Office Action of July 17, 2008. Applicants contend that Applicants' arguments of October 17, 2008 were not properly considered or responded to by the Examiner. The Examiner's rejection and subsequent responses were legally and factually deficient because the Examiner failed to adequately show where the cited reference teaches or suggests an oligonucleotide covalently lined a hydrophilic polymer via an acid cleavable linkage.

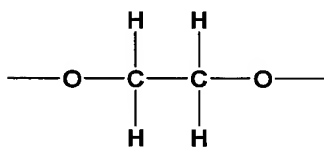
Claims 1-7 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Tullis (U.S. Pat. No. 4,904,582). Specifically, the Examiner alleged that Tullis discloses an "acid cleavable linkage including an acetal bond." Office Action, pg. 4, 1<sup>st</sup> ¶. In the Advisory Action, the Examiner further clarified her rejection, stating that "Tullis disclose 'O-(CH<sub>2</sub>)<sub>n</sub>O-' wherein 'n is usually in the range of 2-20', which does not exclude the bond wherein n=1." Advisory Action, pg. 2, 1<sup>st</sup> ¶. Applicants respectfully traverse this rejection.

Under 35 U.S.C. § 102, a claim can only be anticipated if every element in the claim is expressly or inherently disclosed in a single prior art reference. *See Kalman v. Kimberly Clark Corp.*, 713 F.2d 760, 711 (Fed.Cir. 1983), *cert. denied*, 465 U.S. 1026 (1984); also *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987). "Anticipation under § 102 can be found only when the reference discloses *exactly* what is claimed . . . ." *Titanium Metals Corp. v. Banner*, 778 F.2d 775 (Fed. Cir. 1985) (emphasis added).

Claim 1 features an acid-cleaveable linkage. The Examiner has not provided evidence, or even suggested, that an acid cleavable linkage, e.g., an acetal bond, is expressly disclosed in Tullis. As one of skill in the art can appreciate, an acetal bond is of the generic formula:



In Tullis, various bonds are disclosed, including what the Examiner mistakenly characterizes as an acetal bond as found on col. 4, line 7: "-O(CH<sub>2</sub>)<sub>n</sub>O-" wherein n is usually in the range of 2 to 20 (col. 4, line 15). Thus, the closest bond expressly described in Tullis is:



Thus, Tullis does not expressly teach an acetal bond, nor an acid cleaveable bond.

However, the Examiner has alleged that Tullis inherently discloses an acetal bond. As mentioned supra, the Examiner interprets that linkages of Tullis would include an acetal bond, since Tullis notes "n is usually in the range of 2-20, which does not exclude the bond wherein n=1." Advisory Action, pg. 2, ¶1. Thus, the Examiner interprets the term "*usually* is in the range 2-20" to inherently include n = 1. In other words, the Examiner alleged that n=1 is inherently anticipated by the range "usually in the range 2-20."

"To serve as an anticipation when the reference is silent about the asserted inherent characteristic, such gap in the reference may be filled with recourse to extrinsic evidence. Such evidence must make clear that *the missing descriptive matter is necessarily present* in the thing

described in the reference." *Continental Can Co. USA v. Monsanto Co.*, 948 F.2d 1264, 1268 (Fed. Cir. 1991) (emphasis added).

Even if, *arguendo*, one considered that  $n=1$  sometimes fall within the range of " $n$  is usually in the range 2-20," this would still not constitute an inherent anticipation, since " $n$  is 1" is *not necessarily present* in the disclosed range, i.e.,  $n=1$  is not always in the range "usually in the range 2-20." Thus, an acid cleavable linkage, e.g., an acetal bond is not inherently disclosed in compounds of Tullis.

Thus, since each and every element of claim 1 is not found in Tullis, either expressly or inherently, claim 1 is not anticipated by Tullis. Claims 2-7 depend from claim 1, and thus they are also not anticipated by Tullis. For at least the above arguments, Applicants respectfully request that the rejection of claims 1-7 under 35 U.S.C. § 102 in view of Tullis be withdrawn.

#### ***Other Rejections***

Claim 8 was rejected under 35 U.S.C. § 103 as allegedly being unpatentable over Raschella *et al.* (*Cancer Research* 52:4221-4226 (1992)) and Tullis. Claim 8 is ultimately dependent on claim 1.

To establish a *prima facie* case of obviousness, the art cited by the Examiner must (1) teach all of the claim limitations; (2) provide a suggestion or motivation to those of ordinary skill in the art to make the claimed composition; and (3) reveal that one of ordinary skill would have a reasonable expectation of success in doing so. *See In re Vaeck*, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991); *see also* M.P.E.P. § 706.02(j).

Claim 1 features an acid cleavable linkage. As noted above, Tullis does not either expressly or inherently disclose an acid-cleavable linkage. Raschella *et al.* does not cure the deficiencies of Tullis, since it also does not disclose an acid-cleavable linkage. Since all of the elements of claim 1 are not present in either of the cited documents, or a combination thereof, the present invention cannot be obvious in light of these two documents. Upon consideration of the above, Applicants respectfully request that the rejection of claim 8 under 35 U.S.C. § 103 be withdrawn.

***Conclusion***

As discussed above, the Examiner's rejection and subsequent responses were legally and factually deficient because the Examiner maintained her rejection, but failed to adequately show where the cited reference teaches or suggests an oligonucleotide covalently lined a hydrophilic polymer via an acid cleavable linkage. Applicants respectfully request that the rejections be withdrawn.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Scott M. Woodhouse  
Agent for Applicants  
Registration No. 54,747

Date: December 17, 2008

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